STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Paul R. LePage
Governor

Anne L. Head, Esq.
Commissioner

Geraldine L. Betts
Administrator

TO: Pharmacists and Pharmacies
From: Jeri Betts, Board Administrator
Date: August 30, 2012
RE: PL Chapter 577 takes effect August 30, 2012 (corrected version updating board email address)
An Act to Allow for Timely Access to and Enhanced Administration of All Vaccines
http://www.mainelegislature.org/legis/bills/display_ps.asp?snum=125&paper=HP1267&PID=1456
cc: Members, Maine Board of Pharmacy

This bill:

1) Expands the vaccines available to pharmacist who are certified to administer.
2) Clarifies where a vaccine clinic may be held. Current law states "within or outside." The new law changes the word "inside" to "within" and adds "off the pharmacy's premises."
3) Adds a one-time vaccine clinic plan approval requirement by the board.

Board Rule Chapter 4-A will be updated to reflect the new law change on vaccines that may be administered and update references where a clinic may be held. With regard to rules on the operation of drug administration clinics, guidelines are currently in place under Board Rule Chapter 4-A, Sec 3 and will be the baseline for considering one-time approval of the plan of operation of a vaccine administration clinic. Following is a quick cut-out reference for your convenience. A copy of the full text of Chapter 4-A is available online http://www.maine.gov/sos/cec/rules/02/chaps02.htm#392. The rules may be subject to updates with the Board's upcoming review of certain rules, however, for now the current rule in place is the guide for approving a vaccine clinic plan.

When submitting your plan, please be sure use Chapter 4-A, Sec. 3 as your guide. Please be as detailed as possible to avoid any delays in obtaining approval and please provide a contact name, phone number and email address in the event that we have questions. A letter will be sent to you to confirm acceptance and approval of the plan. Please be sure to indicate your preferred method of notice; email or regular mail and provide the appropriate address information. Upon receiving your request for a plan approval, it will be expedited as quickly as possible, however, please allow for a 2-3 day turn around response.

Transmittal method:

- By email submit to: pharmacy.board@maine.gov
- If by email, to expedite processing put this phrase in the subject line: VACCINE CLINIC
- By regular mail: see our mailing address under my signature line below.

Board Rule Chapter 4-A;

3. Operation of Drug Administration Clinics

1. **Site Suitability**

A drug administration clinic must be located in a sanitary, well-maintained, adequately-equipped space that is appropriately sized for the expected patient volume and facilitates interaction among clinic staff and patients.

2. **Written Plan of Operation**

The pharmacist holding a certificate of administration or pharmacy that operates a drug administration clinic shall develop a written plan of operation prior to conducting the clinic, and shall ensure that the plan is complied with during operation. The plan must, at a minimum:

A. Require that any non-health care personnel who assist at the clinic have no contact whatsoever with drugs, immunizations, needles or syringes;

B. Include a specific protocol for prevention of administration errors (e.g., administration of incorrect drug or incorrect dose to patient; administration of drug to wrong patient);

C. Include procedures for the orderly management and flow of patients through the clinic both pre- and post-administration;

D. Include a specific protocol for performing the following procedures

(1) Verification (Section 2(1));

(2) Assessment (Section 2(2));

(3) Provision of vaccine information statement and discussion of possible adverse reactions (Section 2(3));

(4) Obtaining written informed consent (Section 2(4)); and

(5) Issuance of certificate of immunization (Section 2(5));

E. Incorporate the protocol for observing patients following administration required by Section 1(5) of this chapter. Clinic staff shall strongly recommend that all patients remain in the immediate vicinity of the vaccination site for the post-administration observation period specified in the treatment protocol. To facilitate patient compliance, the operator of the clinic shall make a comfortable sitting area available in the immediate vicinity of the administration site. The sitting area must be of adequate size and must be suitably equipped to accommodate the flow of patients for the full duration of the post-administration observation period;

F. Include a protocol for the safe storage and transportation of drugs and immunizations to ensure that the vaccine remains viable until the point of administration;

G. Include procedures to ensure that an adequate number of epinephrine and diphenhydramine syringes and other emergency medical supplies will be available for use in case a patient has an adverse reaction to the drug or vaccination administered; and

H. Include a protocol for infection control. Standard precautions to minimize the risks of spreading disease during vaccine administration must be in place. The protocol must include, at a minimum, the following provisions:

(1) *Handwashing*. Hands must be washed thoroughly with soap and water or cleansed with an alcohol-based waterless antiseptic between patients, before vaccine preparation or any time hands become soiled;

(2) *Gloving*. Gloves are not required to be worn when administering vaccines unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on the hands. It is important to remember that gloves cannot prevent needlestick injuries;

(3) *Needlestick Injuries*. Needlestick injuries must be reported immediately to a lead person, with appropriate care and follow-up given. Safety needles or needle-free injection devices should be used if available to reduce the risk of injury;

[**NOTE**: For more information on needle-free injection technology, see the CDC website: http://www.cdc.gov/vaccinesafety/vaxtech/nfit/.]

(4) *Equipment Disposal*. Used needles may not be detached from syringes, recapped or cut before disposal. All used syringe/needle devices must be placed in puncture-proof containers to prevent accidental needlesticks and reuse. Empty or expired vaccine vials are considered medical waste and are subject to Chapter 900 of the rules of the Department of Environmental Protection, “Biomedical Waste Management Rules;” and

[**NOTE**: The operator of a drug administration clinic may be required to register as a biomedical waste generator with the Department of Environmental Protection.]

(5) *Vaccine Preparation.* Proper vaccine handling and preparation is critical in maintaining the integrity of the vaccine during transfer from the manufacturer's vial to the syringe and ultimately to the patient.

3. **Clinic Personnel**

At the conclusion of a drug administration clinic the pharmacist holding a certificate of immunization or pharmacy that conducted the clinic shall attach to the written plan of operation for that clinic a list that identifies, by name and position:

A. The lead person or persons who were responsible for operation of the clinic; and

B. All pharmacists holding a certificate of administration, pharmacy technicians, student interns, other health care personnel and non-health care personnel who staffed or assisted at the clinic.

4. **Retention of Records**

Records received or created by a pharmacy or pharmacist pursuant to this chapter are subject to the record retention and production requirements of Chapter 24 of the board's rules.

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